RADIADYNE
REDEFINING RADIATION THERAPY

EMERGO GROUP

K120344
MAY - 3 2012

5. 510(K) SUMMARY

Submission Correspondent

Company Name:	Emergo Group, Inc.
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Submission Date:	January 16, 2012
Website:	www.emergogroup.com

Submission Sponsor

Company Name:	RadiaDyne, LLC (Specification Developer)
Company Address:	11931 Wickchester Lane Suite 360 Houston, TX 77043
Country:	USA
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Device Classification

Device Trade Name:	RadiaPak™ Brachytherapy Applicator Balloon Device
Product Classification Name:	System, Applicator, Radionuclide, Remote-Controlled
Product Code:	JAQ

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Regulation Number: 892.5700

Classification Panel: Radiology

Regulatory Class: Class 2

Predicate Devices

1. Capri™ Applicator (K092822)
2. Alatus® Vaginal Balloon Packing System (K092534)

Indications for Use

The RadiaPak™ Brachytherapy Applicator Balloon Device is a single use, non-sterile, disposable, inflatable, non-powered positioning device, manufactured without the use of latex, intended to be used on a daily treatment basis to position and stabilize the brachytherapy radiation delivery applicator within the vagina or rectum during brachytherapy radiation therapy procedures, x-ray, or computed tomography (CT) exam. The placement of the balloon device requires a physician or physician directed healthcare professional.

Device Description

The RadiaPak™ Device is designed to position and stabilize the brachytherapy applicator and to space the applicator surface from the targeted vaginal or rectal mucosa during computed tomography and brachytherapy procedures. The proposed device is a latex free balloon and can be inflated with either air or saline, is provided non-sterile, and is intended for single use.

Predicate Device Comparison

Comparison Of RadiaPak™ vs. Alatus® vs. Capri™ Devices			
Device Information	**RadiaPak™**	**Alatus® (K092534)**	**Capri™ (K092822)**
Product Code	JAQ	JAQ	JAQ
Regulation Number	892.5700	892.5700	892.5700
Classification Name	System, applicator, radionuclide, remote-controlled	System, applicator, radionuclide, remote-controlled	System, applicator, radionuclide, remote-controlled
Device Material	Polyurethane (balloon/shaft)	Polyurethane (balloon/shaft)	PVC (bulb/lumens)

Flexible	Yes	Yes	Yes
Treatment Area	Vaginal or rectal mucosa	Vaginal mucosa	Vaginal or rectal mucosa
Body Contact Area	Mucosal Membrane	Mucosal Membrane	Mucosal Membrane
Procedure Time	≈ ≤ 90 minutes	≈ ≤ 90 minutes	≈ ≤ 90 minutes
Single Use	Yes	Yes	Yes
Supplied Sterile	No	No	Yes
Inflatable	Yes	Yes	Yes
Pressurized With	Air, saline, water	Air, saline, water	Air or saline
Connection Type	Stopcock valve	Stopcock valve	Not applicable
Expands	Yes	Yes	Yes
Deflates	Yes	Yes	Yes

Non-Clinical Data – Biocompatibility & Performance Testing

As part of demonstrating the safety and effectiveness of the RadiaPak™ Device and in showing substantial equivalence to the predicate devices, RadiaDyne performed biocompatibility testing in accordance with ISO 10993-1, as well as performance testing to determine balloon fill volume and fill pressure.

Clinical Data

RadiaDyne's is not submitting any clinical data in support of its 510(k) submission to the FDA for the RadiaPak™ Device as no such clinical data was submitted by VivaRay for its Capri™ Applicator or by RadiaDyne for its Alatus® Vaginal Balloon Packing System.

Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different technological characteristics, but it can be demonstrated that the new device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness compared to the predicate device.

It has been shown in this 510(k) submission that the differences between the RadiaPak™ Brachytherapy Applicator Balloon Device and both the Capri™ Applicator and the Alatus® Vaginal Balloon Packing System do not raise any questions regarding its safety and effectiveness. RadiaDyne's RadiaPak™ Device, as designed and manufactured, is therefore determined to be substantially equivalent to the Capri™ and Alatus® devices previously cleared under K092822 and K092534, respectively.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

RadiaDyne, LLC
% Mr. Stuart R. Goldman
Senior Consultant
Emergo Group, Inc.
611 West 5th Street, Third Floor
AUSTIN TX 78701

MAY - 3 2012

Re: K120344
Trade/Device Name: RadiaPak™ Brachytherapy Applicator Balloon Device
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ and IYE
Dated: January 16, 2012
Received: February 3, 2012

Dear Mr. Goldman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K120344

The RadiaPak™ Brachytherapy Applicator Balloon Device is a single use, non-sterile, disposable, inflatable, non-powered positioning device, manufactured without the use of latex, intended to be used on a daily treatment basis to position and stabilize the brachytherapy radiation delivery applicator within the vagina or rectum during brachytherapy radiation therapy procedures, x-ray, or computed tomography (CT) exam. The placement of the balloon device requires a physician or physician directed healthcare professional.

Prescription Use X (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

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